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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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11/19/2004

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,922

Applicant(s)

GAYED, ATEF

Examiner

Raymond J Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. 11162004.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

CLAIMS 1-10 AND 10-53 ARE PRESENTED FOR EXAMINATION

Applicant's Amendment filed October 21, 2004 has been received and entered into the application. Accordingly, claims 31, 32, 37, 40, 46 and 49 have been amended.

In view thereof, the rejection of claims 1-7, 10-39, 45, 48, 51 and 53-53 under 35 USC § 112, second paragraph, as set forth in the previous Office action dated June 16, 2004 is withdrawn.

Claim Objection

Claim 32 is objected to because of the following informality (necessitated by applicant's amendment):

At line 2, the term "by" should be set forth before "suppository". Appropriate correction is required.

Claim Rejection - 35 USC § 112, Second Paragraph

Claims 1-7, 10-39, 45, 48, 51 and 53-53 remain rejected under 35 U.S.C. 112, second paragraph for the reasons of record as set forth in the previous Office action dated June 16, 2004 at page 2.

Applicant's arguments at page 13 of their amendment have been carefully considered, but fail to persuade the Examiner of error in his determination.

In particular, applicants have taken the position that by the expression, "not formulated for topical administration", the claimed subject matter would be definite and that one of skill in the art would understand what applicant is claiming as their invention.

Art Unit: 1614

The Examiner cannot agree because whether or not a particular formulation is "not formulated for topical administration" would be open to subjective interpretation and thus the skilled artisan would not be reasonably apprised of which formulations were included or excluded by the present claims. As an example, if one considers a simple aqueous solution consisting of water and the claim specified active agents, would one skilled in the art be reasonably apprised of whether it was a solution covered by the present claims or not? The answer is of the same nature as the present claims: uncertain. It would be uncertain because one would have to rely upon the intent of a person in possession and having knowledge of the solution to determine its intended use. Such intent is not "set in stone", but is variable and subjective in nature. While a simple aqueous solution is used in the example above, the same would hold true for other types of formulations such a liquid, suspension, emulsion, mixture, aerosol or a powder.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention." (MPEP 2173).

Because the expression "not formulated for topical administration" would invite subjective interpretations of whether or not a particular formulation was included by or excluded from the present claims, it is the Examiner's position that the public would not be informed of

Art Unit: 1614

the boundaries of what constitutes infringement of the present claims and thus the claims do not meet the requirements of 35 U.S.C. § 112, second paragraph.

Claim Rejection - 35 USC § 103

Claims 1, 2, 16, 29, 31-34 and 37-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bergamini et al., (U.S. Patent No. 5,597,560), already of record, for the reasons of record as set forth in the previous Office action .

Applicant's amendments and arguments have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

In particular, applicant has argued that because the patentees' formulation are administered topically and the present claims "have been amended to remove the recitations of dosage forms/routes of administration that would be considered exclusively topical", the present claims are patentable over that which is disclosed or suggested by the patentees.

The Examiner cannot agree because the dosage forms of the patentees, while being taught to be administered topically, are not clearly distinguishable over the dosage forms presently claimed. The present claims are not directed to any particular method of administration which would not have been obvious over the topical administration taught by the patentees. Also, even given the teachings of Remington's, it is not seen that the formulations of the patentees would not satisfy the structural, physical and chemical requirements of the presently claimed formulations which are "not formulated for topical administration" or "administrable", i.e., capable of being administered, orally.

Accordingly, for the reasons above as well as those of record, the claims are deemed properly rejected.

Art Unit: 1614

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

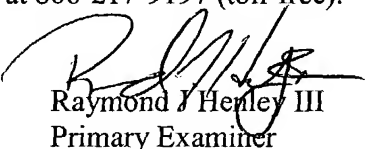
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Application/Control Number: 10/031,922

Page 6

Art Unit: 1614

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J. Henley III
Primary Examiner
Art Unit 1614

November 16, 2004